WEAVER BROS., INC.

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November 19, 2004

895 EAST MAIN STREET

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Division of Dockets Management Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504

Dear Sir or Madam:

I am writing to comment on the Food and Drug Administration's proposed rule on Salmonella Enteritidis in shell eggs. I am an egg producer with operations in Versailles, Ohio. As an egg producer, I take pride in delivering a safe product to my customers. Food safety is in my interest as a farmer and small business operator. FDA should review medical information from the Centers for Disease Control, which finds egg quality assurance programs have already made a difference wherever they have been used. Producers and states have been implementing these plans voluntarily, with no federal mandate. In addition, I urge the FDA not to engage in confrontational and threatening inspections.

I am already regulated by many different federal and state agencies. Even when the aim of regulation is good, the burden of complying can be heavy, especially on farms and other small businesses. I respectfully urge FDA to minimize the additional burden.

- 1. Ohio has a successful program in which we participate. FDA should thoroughly review all existing state and private egg quality assurance programs to see if they already provide protection equivalent to what FDA is seeking. If so, then the producers who are in compliance with one of these plans should be considered to be in compliance with FDA's regulations.
- 2. Carry out inspections and enforcement through federal and state agencies that already regulate our industry. The Agricultural Marketing Service already inspects egg packing facilities four times a year under the Shell Egg Surveillance Program, often in cooperation with state agencies. AMS and the states are knowledgeable of the egg industry, and using them will avoid diverting FDA employees away from homeland security, import inspections and other work.

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I would also suggest that FDA needs more input from scientists who are experts in egg and poultry science. Several parts of the proposal should be changed because they are either impractical, unnecessarily costly or in conflict with sound science.

- The proposed rule does nothing to encourage vaccination, even though it is a highly effective means of controlling SE. I suggest that producers have the ability to demonstrate the effectiveness of a vaccination program and if they can do so, then they should be able to follow a protocol of a single environmental test shortly before depopulation. Our company does vaccinate.
- FDA's requirement for a wet cleaning is unrealistic. In winter months, it is not practical to do this in large parts of the United States. FDA should not impose a requirement that producers cannot carry out. FDA says in the proposed rule that some studies show an increase in SE after a wet cleaning -- and yet the agency is still proposing to require wet cleaning! FDA should make the wet cleaning optional, and require only a dry cleaning after an environmental positive.
- FDA's requirement that eggs held more than 36 hours be refrigerated at 45°F is also unrealistic and unnecessary. This would mean new refrigeration requirements every weekend and holiday for further processors who have production capacity -- and yet the eggs will immediately be pasteurized, killing the bacteria! In addition, this requirement could actually be detrimental to food safety for eggs that go into the table market. When the eggs are washed, there will be a higher incidence of checks and cracks if they have previously been refrigerated, simply because of the sudden change in temperature. FDA should lengthen the 36-hour limit to something more realistic, like 72 hours. FDA should then require refrigeration at 55°F unless the eggs are held more than a week, then impose the 45°F requirement if necessary.
- FDA's biosecurity requirements should be more flexible. Biosecurity is important, but the extensive steps the agency lists will be extremely burdensome on smaller farms, especially off-line contract farms. Along with other costs, these requirements could cause further consolidation in our industry, with some smaller operations unable to afford the additional labor and compliance costs. Yet our government always professes to be concerned about increasing concentration in agriculture.

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In closing, I repeat that my farm is dedicated to delivering a safe product to our customers. We will always comply with the law and regulations to the best of our ability. But we need regulations that are flexible, reasonably applied, and scientifically based if we are to survive as a business. In agriculture, we usually cannot pass on increased costs to our customers. The producer ends up absorbing the cost of regulations. I strongly urge you to make the changes that producers are asking, so that this regulation can be workable for our industry.

Sincerely,

WEAVER BROS., INC.

Timothy J. Weaver

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President

TJW/kd